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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/617,389	07/17/00	LOK S	96-06C3

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EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1647	6

DATE MAILED: 09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/617,389	LOK et al.
Examiner	**Art Unit**
Christine Saoud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-30* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to DNA, vectors, hosts and recombinant methods of use, classified in at least class 435, subclass 69.4, for example.

II. Claims 7, 21-26, drawn to a polypeptide, classified in at least class 530, subclass 350, for example.

III. Claims 8-10, drawn to antibodies, classified in at least class 530, subclass 387.1, for example.

IV. Claim 11, drawn to a method of enhancing the viability of sperm by administration of a polypeptide, classified class 514, subclass 2, for example.

V. Claims 12-13, drawn to a method of enhancing sperm motility by administration of a polypeptide, classified in class 514, subclass 2

VI. Claim 14, drawn to a method of enhancing an egg-sperm interaction by administration of a polypeptide, classified in class 514, subclass 2, for example.

VII. Claims 15-17, drawn to a method of enhancing fertilization by administration of a polypeptide, classified in class 514, subclass 2, for example.

VIII. Claims 18-19, drawn to a method of contraception by administration of an antagonist, classified in class undetermined, subclass undetermined.

IX. Claim 20, drawn to a method of immunocontraception by administration of a polypeptide, classified in class x, subclass x, for example.

X. Claims 27-28, drawn to a method of detecting polypeptides, classified in class x, subclass x, for example.

XI. Claims 29-30, drawn to a method of detecting polynucleotides, classified in class x, subclass x, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be made by an entirely different method, such as by isolation from nature, rather than by the recombinant methods of Group I.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the polynucleotides of Group I are not required for the production of the antibodies of Group III. Additionally, the compounds are structurally and functionally distinct.

4. Inventions I and (IV-XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the polynucleotides of Group I are not required for the methods of Groups IV-VIII.

5. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used in an entirely different method, such as in any of the methods of Groups IV-VII or IX, rather than for generating the antibodies of Group III. Furthermore, the compounds of Groups II and III are physically and functionally distinct, and cannot be used one for the other.

6. Inventions II and (IV-VII, IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used in an entirely different method, such as in a method of generating antibodies rather than in any of the methods of Groups IV-VII or IX.

7. Inventions II and (VIII, X-XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the polypeptides of Group II are not required for the methods of Groups VIII, X-XI.

8. Inventions III and (IV-VII, IX, XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the antibodies of Group III are not required for any of the methods of Groups (IV-VII, IX, XI).

9. Inventions II and (VIII, X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used in an entirely different method, such as in a method of purifying the polypeptide rather than in the methods of Groups VIII or X.

10. Inventions IV-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because the methods of Groups IV-XI have different goals, method steps, and/or starting materials, and are not required one for the other.

Additional Restriction Requirement

11. Upon the election of any one of Groups I-XI, Applicant is further required to elect a single invention of polynucleotide, polypeptide, antibody (wherein a single molecular embodiment of polypeptide must be identified to which the antibody is to bind), and various methods which

require an identification of a single molecular embodiment of polynucleotide, polypeptide, or antibody for practice in the method. For example, distinct inventions of polypeptide include, but are not limited to:

having an amino acid sequence of SEQ ID NO:2 from residue 53 to 162,

having an amino acid sequence of SEQ ID NO:13 from residue 55 to 172,

having an amino acid sequence of SEQ ID NO:13 from residue 201 to 213,

having an amino acid sequence of SEQ ID NO:2 from residue 24 to 51 (B chain) and of SEQ ID NO:2 from residue 163 to 188 (A chain),

having an amino acid sequence of SEQ ID NO:2 from residue 24 to 52 (B chain) and of SEQ ID NO:2 from residue 163 to 188 (A chain),

having an amino acid sequence of SEQ ID NO:13 from residue 23 to 53 (B chain) and of SEQ ID NO:13 from residue 173 to 198 (A chain),

having an amino acid sequence of SEQ ID NO:13 from residue 23 to 54 (B chain) and of SEQ ID NO:13 from residue 173 to 198 (A chain),

having an amino acid sequence of SEQ ID NO:13 from residue 23 to 54 (B chain) and of SEQ ID NO:13 from residue 173 to 199 (A chain),

having an amino acid sequence of SEQ ID NO:13 from residue 23 to 54 (B chain) and of SEQ ID NO:13 from residue 173 to 200 (A chain),

encoded by a polynucleotide of SEQ ID NO:1,

encoded by a polynucleotide of SEQ ID NO:12.

This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/ polypeptides/antibodies/ and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups I-XI, Applicant is additionally required to elect a single nucleic acid, polypeptide, or antibody. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 28, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud